REMARKS

Herewith, claims 35-36 are canceled and claims 32-33, 37-40, and 43-44 are amended. Accordingly, claims 1-34, 37-40, and 43-44 are presently pending, with claims 1-4, 9-34, and 43-44 being withdrawn from consideration as directed to a non-elected invention. Thus, only claims 5-8 and 37-40 are presently under consideration.

At the outset, Applicants wish to thank the Examiner for acknowledging the allowability of elected claims 5-8. Applicants respectfully submit that the instant amendments to elected claims 37-40 place them in condition for allowance as well. In particular, in an effort to expedite prosecution, Applicants have herewith:

- amended claim 37 to depend from allowed claim 5 and thereby include a complete description of the crystalline polymorphic "form B" of N- N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate;
- amended claim 38 to depend from claim 37 and include a complete description of the crystalline polymorphic "form A" of N- N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate; and
- amended claims 39 and 40 to address antecedent basis concerns.

In addition, in an effort to promote rejoinder of withdrawn method claims, Applicants have amended method claims 32 and 33 to depend indirectly from method claim 24, which, in turn, depends from allowed claim 5. Applicants have also amended method claims 43 and 44 to depend from composition claim 37, which also depends from allowed claim 5. As such, claims 32, 33, 43, and 44 are ripe for reconsideration and rejoinder.

Applicants respectfully submit that the amendments presented herewith place the instant application in condition for allowance without introducing new matter. To that end, Applicants

respectfully submit that support for the claims as amended is found in the application as originally filed, particularly in original claims 1-3 and 5-7. However, Applicants reiterate that the instant amendments are presented solely for the purpose of expediting prosecution and should not be construed as Applicants' agreement with or acquiescence to the grounds of rejection previously set forth.

Turning now to the outstanding Office Action of July 17, 2009:

Election/Restriction

Applicants wish to thank the Examiner for reconsidering the Restriction/Election Requirement of March 16th and further affirm their election of the invention of Group II, directed to a Form B of rizatriptan benzoate and encompassing claims 5-8 and 37-40. However, given the allowance of composition claims 5-8 and the allowable condition of composition claims 37-40 (which now depend directly or indirectly from allowed claim 5), Applicants respectfully submit that the withdrawn methods of making (claims 24-34 of Group IV) and the withdrawn methods of using (claims 43-44 of Group V) are ripe for rejoinder. Accordingly, Applicants respectfully request rejoinder, reconsideration and allowance of pending claims 24-34 and 43-44.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 37-40 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. According to the Examiner, the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the Examiner asserts that metastable compounds, such as the crystalline polymorphic Form B of N- N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate (rizatriptan benzoate) recited in claim 5, tend to resort back to their most thermodynamically

stable forms (i.e., a form having a different X-ray diffraction pattern), particularly when pharmaceutically formulated. Accordingly, one of skill in the art would expect a solution prepared from the specific crystalline form of claim 5 (i.e., a formulation of claim 37) to contain the free form of the compound. Given that the specification fails to provide steps for ensuring that the claimed pharmaceutical compositions will maintain the specifically described forms and will not resort back to the free form or the most thermodynamically stable form of the compound, one of ordinary skill, without further direction, would be unable to maintain a specific metastable crystalline form upon preparation into a pharmaceutical composition, a process that may require milling or the formation of a solution.

Applicants respectfully disagree. It is well settled that a patent specification is presumed to be in compliance with the enablement requirement of 112, first paragraph, and thus, the burden is on the Patent Office to establish a reasonable basis to question enablement. The test of enablement is whether one reasonably skilled in the art could make and use the claimed invention (herein a pharmaceutical composition) from the disclosures in the patent coupled with information known in the art without undue experimentation. For an Examiner to sustain a rejection on the grounds of enablement, she must provide evidence (as opposed to conjecture and/or speculation) that the claimed composition could not be made without undue experimentation.

In this case, the Examiner relies on a limited fact -- that certain polymorphic forms of other active ingredients have been known to be converted to other forms during medicament processing, particularly under certain specific processing conditions -- to support a broad conclusion -- that such changes necessarily occur across the board, including in the context of rizatriptan form B. However, whether or not one polymorphic form readily transforms to another polymorphic form in the context of water treatment, composition milling, or the like is highly dependent on the specific active ingredient as well as the specific polymorphic form. In this case, there is no evidence that the polymorphic form B of rizatriptan set forth in pending claims 37-40 is particularly sensitive or susceptible to polymorphic change in the course of pharmaceutical preparation. Accordingly, it is

improper for the Examiner to simply presume, without further supporting evidence or specific indication in the art, that the presently claimed crystalline polymorphic form B of rizatriptan will automatically or spontaneously convert to another polymorphic form when it is processed to a medicament. Accordingly, Applicants respectfully dispute the Examiner's allegation of inevitable transformation.

In any event, one of ordinary skill in the art, aware of course of the possibility that a metastable polymorphic form might change to a thermodynamically more stable form during the preparation of a pharmaceutical composition, could routinely take care to avoid process steps that might be conducive to polymorphic conversion. For example, he would choose to avoid use a solvent for the active ingredient or other harsh reaction conditions and instead embrace the extensive number of alternate medicament preparation methods that do not include such problematic steps. Illustrative examples of such alternate preparation methods are set forth in the as-filed specification, for example on page 8, second paragraph wherein a process for the preparation of a pharmaceutical composition comprising addition of an effective amount of the pharmaceutically active ingredient composition to a pharmaceutically acceptable carrier is described. Such an addition cannot and will not affect the polymorphic form of rizatriptan. Accordingly, the mixture of rizatriptan form B and pharmaceutically active carrier can then, for example, be filled into a capsule or a sachet or pressed into a tablet, another process that does not affect the polymorphic form of rizatriptan. Thus, even if a skilled person were to, *arguendo*, encounter problems with a certain preparation method for a medicament of rizatriptan form B (a presumption for which there is no evidence), the present application contains sufficient information to choose a preparation method which is suitable to prepare a pharmaceutical composition as claimed. Thus, Applicants respectfully submit that, contrary to the Examiner's suggestion, one reasonably skilled in the art could indeed make and use the claimed invention (from the disclosures in the patent coupled with information known in the art without undue experimentation.

Accordingly, Applicants respectfully submit that the claims as amended herewith meet the enablement requirement set forth in 35 U.S.C. § 112, first paragraph. As such, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections of claims 37-40 in view of the amendments and remarks herein.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 37-40 stand further rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, the claims fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that the term "crystalline polymorphic form B" is not descriptive and does not define the polymorph that applicant is claiming.

In an effort to expedite prosecution, Applicants have amended claims 37 and 38 as noted above. In particular, claim 37 has been amended to depend from allowed claim 5 and thereby includes a complete description of the crystalline polymorphic "form B" of N- N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate. Likewise, claim 38 has been amended depend from claim 37 and to further include a complete description of the crystalline polymorphic "form A" of N- N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate. Minor amendments have been introduced into claims 39 and 40 to address potential antecedent basis issues.

Accordingly, Applicants respectfully submit that the claims as amended herewith meet the threshold requirements for clarity and precision set forth in 35 U.S.C. § 112, second paragraph. As such, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections of claims 37-40 in view of the amendments and remarks herein.

Rejections under 35 U.S.C. § 102

Claims 37-40 stand further rejected under 35 U.S.C. § 102(b) as being anticipated by Sandquiet et. Al (GB 2315673A). According to the Examiner, Sandquiet teaches pharmaceutical compositions of rizatriptan benzoate useful in the treatment of migraines, such compositions encompassing the claimed polymorphic "Form B".

Applicants respectfully disagree and submit the Examiner's characterization of the prior art teachings are in error. Nevertheless, in an effort to expedite prosecution, Applicants have amended claim 37 to depend from and therefore include all the limitations of allowed claim 5. Thus, in that claim 5 has been found to distinguish over the prior art, so much the invention of claims 37-40 be deemed distinct therefrom. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 37-40 under 35 U.S.C. § 102(b) in view of the amendments and remarks herein.

CONCLUSION

The outstanding Office Action set a three-month shortened statutory period for response, response being due on or before **October 17, 2009**. In that the Petition for a One-Month Extension of Time extends this deadline to on or before **November 17, 2009**, Applicants respectfully submit that this response is timely and no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. 50-2101.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,
By: /chalin a. smith/

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